

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 6

Complete if Known

| | |
|------------------------|--------------------|
| Application Number | 10/660,202 |
| Filing Date | September 11, 2003 |
| First Named Inventor | Örn Almarsson |
| Art Unit | 1617 |
| Examiner Name | Deirdre R. Claytor |
| Attorney Docket Number | TPI.350C1 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|----------|--------------------------------|-----------------------------|---|---|
| | | Number - Kind Code* (if known) | | | |
| | U1 | US-2,665,277 | 01-05-1954 | Homeyer <i>et al.</i> | All |
| | U2 | US-3,970,651 | 07-20-1976 | Kaplan <i>et al.</i> | All |
| | U3 | US-4,925,674 | 05-15-1990 | Giannini <i>et al.</i> | All |
| | U4 | US-4,927,855 | 05-22-1990 | Lafon | All |
| | U5 | US-4,994,604 | 02-19-1991 | Tung <i>et al.</i> | All |
| | U6 | US-5,023,092 | 06-11-1991 | DuRoss | All |
| | U7 | US-5,521,207 | 05-28-1996 | Graneto | All |
| | U8 | US-5,273,760 | 12-28-1993 | Oshlack <i>et al.</i> | All |
| | U9 | US-5,286,493 | 02-15-1994 | Oshlack <i>et al.</i> | All |
| | U10 | US-5,324,351 | 06-28-1994 | Oshlack <i>et al.</i> | All |
| | U11 | US-5,356,467 | 10-18-1994 | Oshlack <i>et al.</i> | All |
| | U12 | US-5,366,738 | 11-22-1994 | Rork <i>et al.</i> | All |
| | U13 | US-5,472,712 | 12-05-1995 | Oshlack <i>et al.</i> | All |
| | U14 | US-5,510,496 | 04-23-1996 | Talley <i>et al.</i> | All |
| | U15 | US-5,563,165 | 10-08-1996 | Talley <i>et al.</i> | All |
| | U16 | US-5,631,250 | 05-20-1997 | Bunnell <i>et al.</i> | All |
| | U17 | US-5,633,272 | 05-27-1997 | Talley <i>et al.</i> | All |
| | U18 | US-5,703,232 | 12-30-1997 | Bunnell <i>et al.</i> | All |
| | U19 | US-5,736,541 | 04-07-1998 | Bunnell <i>et al.</i> | All |
| | U20 | US-5,753,688 | 05-19-1998 | Talley <i>et al.</i> | All |
| | U21 | US-5,760,068 | 06-02-1998 | Talley <i>et al.</i> | All |
| | U22 | US-5,932,598 | 08-03-1999 | Talley <i>et al.</i> | All |

Examiner
Signature

/Renee Claytor/

Date
Considered

09/10/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RC/

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 6

Complete if Known

| | |
|------------------------|--------------------|
| Application Number | 10/660,202 |
| Filing Date | September 11, 2003 |
| First Named Inventor | Örn Almarsson |
| Art Unit | 1617 |
| Examiner Name | Deirdre R. Claytor |
| Attorney Docket Number | TPI.350C1 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|-----------------------------------|--------------------------------|--|---|
| | | Number - Kind Code* (if known) | | | |
| | U23 | US-5,972,986 | 10-26-1999 | Seibert <i>et al.</i> | All |
| | U24 | US-5,985,902 | 11-16-1999 | Talley <i>et al.</i> | All |
| | U25 | US-6,054,136 | 04-25-2000 | Farah <i>et al.</i> | All |
| | U26 | US-6,132,420 | 10-17-2000 | Dionne <i>et al.</i> | All |
| | U27 | US-6,156,781 | 12-05-2000 | Talley <i>et al.</i> | All |
| | U28 | US-6,245,357 | 06-12-2001 | Edgren <i>et al.</i> | All |
| | U29 | US-6,270,787 | 08-07-2001 | Ayer | All |
| | U30 | US-6,283,953 | 09-04-2001 | Ayer <i>et al.</i> | All |
| | U31 | US-6,287,295 | 09-11-2001 | Chen <i>et al.</i> | All |
| | U32 | US-6,323,266 | 11-27-2001 | Phillips | All |
| | U33 | US-6,333,050 | 12-25-2001 | Wong <i>et al.</i> | All |
| | U34 | US-6,342,249 | 01-29-2002 | Wong <i>et al.</i> | All |
| | U35 | US-6,348,458 | 02-19-2002 | Hamied <i>et al.</i> | All |
| | U36 | US-6,365,185 | 04-02-2002 | Ritschel <i>et al.</i> | All |
| | U37 | US-6,368,626 | 04-09-2002 | Bhatt <i>et al.</i> | All |
| | U38 | US-6,375,978 | 04-23-2002 | Kleiner <i>et al.</i> | All |
| | U39 | US-6,384,034 | 05-07-2002 | Smitchieva <i>et al.</i> | All |
| | U40 | US-6,403,640 | 06-11-2002 | Stoner <i>et al.</i> | All |
| | U41 | US-6,413,965 | 07-02-2002 | Mylari | All |
| | U42 | US-6,420,394 | 07-16-2002 | Supersaxo | All |
| | U43 | US-6,579,895 | 06-17-2003 | Karim <i>et al.</i> | All |
| | U44 | US-6,613,790 | 09-02-2003 | Carter | All |

| | | | |
|--------------------|-----------------|-----------------|------------|
| Examiner Signature | /Renee Claytor/ | Date Considered | 09/10/2010 |
|--------------------|-----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard 1.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RC/

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 6

Complete if Known

| | |
|------------------------|--------------------|
| Application Number | 10/660,202 |
| Filing Date | September 11, 2003 |
| First Named Inventor | Örn Almarsson |
| Art Unit | 1617 |
| Examiner Name | Deirdre R. Claytor |
| Attorney Docket Number | TPI.350C1 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number Number - Kind Code* (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|---|--------------------------------|--|---|
| | U45 | US-7,172,769 | 02-06-2007 | Kararli <i>et al.</i> | All |
| | U46 | US-7,205,413 | 04-17-2007 | Morissette <i>et al.</i> | All |
| | U47 | US-7,446,107 | 11-04-2008 | Remenar <i>et al.</i> | All |
| | U48 | US-7,452,555 | 11-18-2008 | Childs | All |
| | U49 | US-7,459,449 | 12-02-2008 | Keltjens | All |
| | U50 | US-2002/0013357 | 01-31-2002 | Nadkarni <i>et al.</i> | All |
| | U51 | US-2002/0006951 | 01-17-2002 | Hageman <i>et al.</i> | All |
| | U52 | US-2002/0015735 | 02-07-2002 | Hedden <i>et al.</i> | All |
| | U53 | US-2002/0034542 | 03-21-2002 | Thombre <i>et al.</i> | All |
| | U54 | US-2002/0071857 | 06-13-2002 | Kararli <i>et al.</i> | All |
| | U55 | US-2002/0107250 | 08-08-2002 | Hariharan <i>et al.</i> | All |
| | U56 | US-2002/0119193 | 08-29-2002 | Le <i>et al.</i> | All |
| | U57 | US-2004/0029946 | 02-12-2004 | Arora <i>et al.</i> | All |
| | U58 | US-2004/0154890 | 08-12-2004 | Liu | All |
| | U59 | US-2004/0242640 | 12-02-2004 | Desai <i>et al.</i> | All |
| | U60 | US-2005/0070551 | 03-31-2005 | Remenar <i>et al.</i> | All |
| | U61 | US-2007/0015841 | 01-18-2007 | Tawa <i>et al.</i> | All |
| | U62 | US-2007/0293674 | 12-20-2007 | Scoppettuolo <i>et al.</i> | All |
| | U63 | US-7,132,570 | 11-07-2006 | Neckebroek <i>et al.</i> | All |
| | U64 | US- | | | |
| | U65 | US- | | | |
| | U66 | US- | | | |

| | | | |
|--------------------|-----------------|-----------------|------------|
| Examiner Signature | /Renee Claytor/ | Date Considered | 09/10/2010 |
|--------------------|-----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RC/

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

4

of

6

Complete if Known

| | |
|------------------------|--------------------|
| Application Number | 10/660,202 |
| Filing Date | September 11, 2003 |
| First Named Inventor | Orn Almarsson |
| Group Art Unit | 1617 |
| Examiner Name | Deirdre R. Claytor |
| Attorney Docket Number | TPI 350C1 |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | T ² |
|--------------------|-----------------------|---|--------------------------------|--|--|----------------|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | F1 | WO 01/45706 | 06-28-2001 | Pharmacia Corporation | All | |
| | F2 | WO 2002/102376 | 12-27-2002 | Pharmacia Corporation | All | |
| | F3 | WO 2002/10125 | 02-07-2002 | Teva Pharmaceutical Industries Ltd. | All | |
| | F4 | WO 2002/056915 | 07-25-2002 | Cephalon, Inc. | All | |
| | F5 | WO 2005/053612 | 06-16-2005 | Shire Laboratories, Inc. | All | |
| | F6 | WO 96/33193 | 10-24-1996 | Janssen Pharmaceutica N.V. | All | |
| | F7 | JP 54-095589 | 07-28-1979 | Sumitomo Chemical Co. Ltd. | All | |
| | F8 | FR 2,849,029 | 06-25-2004 | Laboratoire L. Lafon | All | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|--|----------------|
| | R1 | BALL, P. "Scandal of crystal design..." <i>Nature</i> , June 20, 1996, pp. 648-650, Vol. 381. | |
| | R2 | BASTIN, R. J. <i>et al.</i> "Salt Selection and Optimization Procedures for Pharmaceutical New Chemical Entities" <i>Organic Process Research & Development</i> , 2000, pp. 427-435, Vol. 4, No. 5. | |
| | R3 | BERNSTEIN, J. <i>et al.</i> "Concomitant Polymorphs" <i>Angew. Chem. Int. Ed.</i> , 1999, pp. 3440-3461, Vol. 38. | |
| | R4 | BOUCHER, E. <i>et al.</i> "Use of Hydrogen Bonds to Control Molecular Aggregation. Behavior of Dipyridones and Pyridone-Pyrimidones Designed to Form Cyclic Triplexes" <i>J. Org. Chem.</i> , 1995, pp. 1408-1412, Vol. 60. | |

Examiner
Signature

/Renee Claytor/

Date
Considered

09/10/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RC/

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 5 of 6**Complete if Known**

| | |
|------------------------|--------------------|
| Application Number | 10/660,202 |
| Filing Date | September 11, 2003 |
| First Named Inventor | Örn Almarsson |
| Group Art Unit | 1627 |
| Examiner Name | Deirdre R. Claytor |
| Attorney Docket Number | TPI 350C1 |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|--|----------------|
| | R5 | BRITTAI, H. G. "Polymorphism in Pharmaceutical Solids, Marcel Dekker, Inc., 1999. pp. 183, 202-208 and 219. | |
| | R6 | CHANG, Y. <i>et al.</i> "An Approach to the Design of Molecular Solids. Strategies for Controlling the Assembly of Molecules into Two-Dimensional Layered Structures" <i>J. Am. Chem. Soc.</i> , 1993, pp. 5991-6000, Vol. 115. | |
| | R7 | COWAN, J. A. <i>et al.</i> "Neutron diffraction studies of the 1:1 and 2:1 cocrystals of benzene-1,2,4,5-tetracarboxylic acid and 4,4'-bipyridine" <i>Acta Cryst.</i> , 2006, pp. o157-o161, Vol. C62. | |
| | R8 | DAVIDOVICH, M. <i>et al.</i> "Detection of Polymorphism by Powder X-Ray Diffraction: Interference by Preferred Orientation" <i>American Pharmaceutical Review</i> , 2004, pp. 10, 12, 14, 16, and 100, Vol. 7, Issue 1. | |
| | R9 | DAVIES, N. M. <i>et al.</i> "Clinical Pharmacokinetics and Pharmacodynamics of Celecoxib. A Selective Cyclo-Oxygenase-2 Inhibitor" <i>Clin. Pharmacokinet.</i> , March 2000, pp. 225-242, Vol. 38, No. 3. | |
| | R10 | DEAN, J. A., <i>Analytical Chemistry Handbook</i> , McGraw-Hill, Inc., 1995, pp. 10.24-10.26. | |
| | R11 | Definition of solvate, The Free Dictionary, http://www.thefreedictionary.com/solvate , accessed online on 21 July 2009, pp. 1-3. | |
| | R12 | DESIRAJU, G. R. "Solid-State Chemistry: Crystal Gazing: Structure Prediction and Polymorphism" <i>Science</i> , October 17, 1997, pp. 404-405, Vol. 278, No. 5337. | |
| | R13 | DOELKER, E. "Physicochemical behavior of active substances. Consequences for the feasibility and stability of pharmaceutical forms" <i>STP Pharma Pratiques</i> , 1999, pp. 399-409, Vol. 9, No.5. | |
| | R14 | DOELKER, E. "Crystalline modifications and polymorphism changes during drug manufacturing" <i>Annales Pharmaceutiques Francaises</i> , 2002, pp. 161-176, Vol. 60, No. 3. | |
| | R15 | DUNITZ, J. D. "Are crystal structures predictable?" <i>Chem Commun.</i> , 2003, pp. 545-548. | |
| | R16 | FEYNMAN, R. P. "There's Plenty of Room at the Bottom" <i>Engineering and Science</i> , February 1960, pp. 22-36. | |
| | R17 | JAIN, N. K. <i>et al.</i> "Polymorphism in Pharmacy" <i>Indian Drugs</i> , 1986, pp. 315-329, Vol. 23, No. 6. | |

Examiner
Signature

/Renee Claytor/

Date
Considered

09/10/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 6 of 6

Complete if Known

Application Number 10/660,202
Filing Date September 11, 2003
First Named Inventor Orn Almarsson
Group Art Unit 1617
Examiner Name Deirdre R. Clayton
Attorney Docket Number TPI 350C1

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No., ¹ | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² |
|--------------------|------------------------|---|----------------|
| | R18 | KIRCHNER, M. T. <i>et al.</i> , Co-crystals with Acetylene: Small is not Simple" <i>Chem. Eur. J.</i> , 2010, pp. 2131-2146, Vol. 16. | |
| | R19 | MOULTON, B. <i>et al.</i> "From Molecules to Crystal Engineering: Supramolecular Isomerism and Polymorphism in Network Solids" <i>Chem. Rev.</i> , 2001, pp. 1629-1658, Vol. 101. | |
| | R20 | MUZAFFAR, N. A. <i>et al.</i> "Polymorphism and Drug Availability" <i>Journal of Pharmacy</i> , 1979, pp. 59-66, Vol. 1, No. 1. | |
| | R21 | OSORIO-LOZADA, A. <i>et al.</i> "Synthesis and determination of the absolute stereochemistry of the enantiomers of adrafinil and modafinil" <i>Tetrahedron: Asymmetry</i> , 2004, pp. 3811-3815, Vol. 15. | |
| | R22 | OTSUKA, M. <i>et al.</i> "Effect of Polymorphic Forms of Bulk Powders on Pharmaceutical Properties of Carbamazepine Granules" <i>Chem. Pharm. Bull.</i> , 1999, pp. 852-856, Vol. 47, No. 6. | |
| | R23 | SHATTOCK, T. R. <i>et al.</i> "Hierarchy of Supramolecular Synthons: Persistent Carboxylic Acid-Pyridine Hydrogen Bonds in Cocrystals That also Contain a Hydroxyl Moiety" <i>Cryst. Growth Des.</i> , 2008, pp. 4533-4545, Vol. 8, No. 12. | |
| | R24 | THAYER, A. M. "Form and Function: The choice of pharmaceutical crystalline form can be used to optimize drug properties, and cocrystals are emerging as new alternatives" <i>Chemical & Engineering News</i> , June 18, 2007, pp. 17-30, Vol. 85, No. 25. | |
| | R25 | U.S. Pharmacopoeia #23, 1995, p. 1843. | |
| | R26 | VILLA, L. A. <i>et al.</i> "Central Nervous System Paracoccidioidomycosis. Report of a Case Successfully Treated with Itraconazole" <i>Rev. Inst. Med. Trop. S. Paulo</i> , July-August 2000, pp. 231-234, Vol. 42, No. 4. | |
| | R27 | ZAWOROTKO, M. J. "Crystal Engineering of Diamondoid Networks" <i>Chemical Society Reviews</i> , 1994, pp. 283-288, Vol. 23. | |
| | R28 | KLEIN, C. L. <i>et al.</i> "Molecular Structure of Two Conformationally Restrained Fentanyl Analogues: cis- and trans-Isomers of N-[3-Methyl-1-[2-(1,2,3,4-tetrahydronaphthyl)-4-piperidinyl]-N-phenylpropanamide" <i>Journal of Pharmaceutical Sciences</i> , November 1985, pp. 1147-1151, Vol. 74, No. 11. | |
| | R29 | | |

Examiner Signature

/Renee Clayton/

Date Considered

09/10/2010

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer: U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RC/